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10/784,088	02/19/2004	Jeffry B. Skiba	JBS 101	7017

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SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER

REIDEL, JESSICA L

ART UNIT	PAPER NUMBER
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3766

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/784,088

Applicant(s)

SKIBA, JEFFRY B.

Examiner

Jessica L. Reidel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02/19/2004, 12/13/2004 and 07/18/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-13, 21-23 and 25-34 is/are rejected.
- 7) ☒ Claim(s) 1-7, 14-20 and 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/04 2/05 8/05 5/06 7/06.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Acknowledgement is made of Applicant's Preliminary Amendments, which were received by the Office on December 13, 2004 and July 18, 2006.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on February 19, 2004, February 22, 2005, August 24, 2005, May 2, 2006 and July 18, 2006 have been acknowledged and are being considered by the Examiner.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the depletion of the first pattern, second pattern and/or conductive lines when brought into contact with the conductive material must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

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application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claims 1, 4, 14 and 20 are objected to because of the following informalities: there appears to exist inadvertent typographical errors in the claims. As to Claim 1, line 15, "printing the a second ink" should read "printing a second ink" instead. As to Claim 4, line 1, the Examiner suggests changing "wherein printing is performed" to read, "wherein the printing is performed" instead. As to Claim 14, line 18, the Examiner suggests changing "the pliable dressing material is to be applied to an area of damaged" to read, "the pliable dressing material is adapted to be applied to an area of damaged" instead. As to Claim 20, line 4, the Examiner suggests changing "to expose to the" to read "exposed to the" instead. Appropriate correction is required.

5. Applicant is advised that should claims 21 and 22 be found allowable, claims 29 and 30 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 8-13 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: a first element including a metal species. The Examiner notes that at lines 7-9 of Claim 8, Applicant claims that the second element includes a different metal species than the first element, however it has not been specified that the first element include a metal species. Since Claims 9-13 depend from Claim 8, the deficiencies of Claim 8 are imputed to all dependent claims.

9. Claim 24 recites the limitation "the pattern" in the eighth line of the claim. There is insufficient antecedent basis for this limitation in the claim. The Examiner notes that a "first pattern" and "second pattern" are defined and is unsure which pattern Applicant intends.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 21 and 25-29 and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Crisp et al. (U.S. 6,522,918) (herein Crisp). As to Claims 21, 25-26, 29 and 32-34, Crisp expressly discloses an electrolytic device, read as an apparatus 20 comprising a base layer or wound dressing, read as an article 22 having a thickness region and body contacting surface,

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collectively read as a primary surface 29, 24 and a pattern of spaced dissimilar metals (silver 34 and zinc 40) on the primary surface 29, 24 where the pattern is to spontaneously produce electrical surface currents when brought into contact with a conductive material (see Crisp Figs. 1a-1f and 2, Abstract, column 2, lines 36-67, column 4, lines 1-10 and 48-67 and columns 4-6).

12. As to Claim 27, Crisp expressly discloses an elastic adhesive layer 60, 64 to secure the article 22 over an area of damaged tissue such that the primary surface 29, 24 is toward the area of damaged tissue (see Crisp Fig. 3, column 5, lines 45-67 and column 6, lines 1-25).

13. As to Claim 28, in addition to the arguments previously presented, Crisp specifies that the article 22 is preferably made from a fabric such as nylon or from polypropylene, polyimide or polyethylene, all of which are inherently flexible.

14. Claims 21, 26-28 and 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Horstmann (U.S. 5,685,837). As to Claims 21, 26, 28-29, 32 and 34, Horstmann discloses a therapeutic system, read as an apparatus (see Horstmann Fig. 1 and Abstract) for carrying out transdermal iontophoretic therapies comprising a flexible backing layer, read as an article/medical instrument 1 having a primary surface where the Examiner interprets the bottom face of the article/medical instrument 1 depicted in Horstmann Fig. 1 to be synonymous with a "primary surface". Horstmann specifies that a pattern of dissimilar materials/electrodes 8, 10, spaced by electrolytic layer 9, are on the primary surface of the article/medical instrument 1 and further that the pattern is to spontaneously produce electrical surface currents when brought into contact with conductive material (see Horstmann Figs. 3 and 4 and columns 3-8).

15. As to Claim 27 and 31, in addition to the arguments previously presented, Horstmann further specifies that the apparatus comprise an insulating layer, read as an elastic adhesive layer

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5 to secure the article over an area of damaged tissue such that the primary surface of the article/medical instrument 1 is toward the area of damaged tissue (see Horstmann Fig. 2 and columns 4-6).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 22-23, 30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horstmann. In addition to the arguments previously presented, Horstmann discloses that the apparatus is made by applying a first pattern of electrodes 3 and a second pattern of electrodes 4 to the primary surface of the article/medical instrument 1 where each pattern 3, 4 is positioned in proximity to each other, yet physically separated from each other (see Horstmann Figs. 1-2). Horstmann specifies that each of the first and second patterns of electrodes 3, 4 may include zinc powder and a polymer binder (first binder in pattern 3 and second binder in pattern 4) (see Horstmann column 3, lines 13-30). Horstmann discloses the claimed invention as discussed above except it is not specified that one of the patterns of electrodes 3, 4 include silver. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make either of the electrodes of Horstmann include silver, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Allowable Subject Matter

18. Claims 1-7 and 14-20 would be allowable if rewritten or amended to overcome the Claim Objections, set forth in this Office Action.
19. Claims 8-13 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office Action.
20. Claim 24 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Carrier et al. (U.S. 5,352,315) teaches that it is known in the art to screen print an ink on a primary surface of an article to create a biomedical electrode for sensing ECG/EKG.

Crisp (U.S. 2006/0015052) (herein Crisp '052) and Crisp (U.S. 2006/0015053) (herein Crisp '053) both teach A wound dressing, comprising: a carrier layer that includes a plurality of first metal particles having an electrochemical potential, a fluid soluble material, and a plurality of second metal particles having a different electrochemical potential from the plurality of first metal particles. Both Crisp '052 and Crisp '053 specify that the first metal particles and second metal particles are suspended alternatively within the fluid soluble material and that a sustained-release galvanic current is produced between the first metal particles and the second metal particles when the carrier layer is subjected to an electrolyte-containing fluid causing erosion of the carrier layer.

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Seiderman (U.S. 4,767,401) discloses iontophoretic administration of medicaments using a wound dressing that spontaneously produces electrical surface currents when in contact with a conductive material.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jessica L. Reidel
Jessica L. Reidel 03/08/07
Patent Examiner
Art Unit 3766

Carl H. Layno
Primary Patent Examiner
Art Unit 3766

Carl H. Layno
CARL LAYNO
PRIMARY EXAMINER
ACTING SPE, AU 3766